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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                   | CONFIRMATION NO.            |
|---|-------------|----------------------|---------------------------------------|-----------------------------|
| 10/552,747  | 10/11/2005  | James Douglas Nelson | PC20548A                              | 2620                        |
| 28523   | 7590        | 11/07/2008           |                                       |                             |
| PFIZER INC.<br>PATENT DEPARTMENT, MS8260-1611<br>EASTERN POINT ROAD<br>GROTON, CT 06340 |             |                      | EXAMINER<br>RODRIGUEZ-GARCIA, VALERIE |                             |
|   |             |                      | ART UNIT<br>1626                      | PAPER NUMBER                |
|   |             |                      | NOTIFICATION DATE<br>11/07/2008       | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

|                              |   |                                      |  |
|------------------------------|---|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/552,747        | <b>Applicant(s)</b><br>NELSON ET AL. |  |
|                              | <b>Examiner</b><br>VALERIE RODRIGUEZ-GARCIA | <b>Art Unit</b><br>1626              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 6-7 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2-5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/13/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of the Claims*

Claims 1-11 are currently pending.

Applicants elected Group IV on page 1 in the response to restriction requirement received on 07/23/08. However, on page 2 of the response, applicants elected Group I. Due that there is no Group IV in the restriction requirement it is understood applicants elected Group I for prosecution. Applicant's election with traverse of Group I, claims 1-7, in the reply filed on 07/23/08 is acknowledged. The traversal is on the ground(s) that examining Groups I and III together does not appear to be overly burdensome. Applicants recognize that the compounds within groups I and III differ with respect to the "special technical feature". Groups I, II and III are related as process for manufacturing products and intermediate compounds. Applicant's arguments are not found persuasive because under PCT rule 13.1 a group of inventions should be so linked as to form a single general inventive concept. However, there is lack of special technical feature between the groups because they do contain different intermediates. The requirement is therefore **maintained**.

Claims 8-11 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/23/08.

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Pursuant to Applicant's response, claims 1-11 are pending, claims 8-11 are withdrawn and claims 1-7 are treated on the merits in this action. This is the first Office Action on the merits of the claims.

***Priority***

This application is a 371 of PCT/IB04/01120 filed on 03/31/2004, which claims priority benefit of provisional application 60/462613 filed on 04/14/2003.

***Note***

The examiner of this application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Valerie Rodriguez-Garcia, Art Unit 1626.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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Claim 1, step (b) states that R is “an acryloyl activated ester equivalent”.

The specification provides only for R is H, (C1-C6)alkyl or phenyl. “Acryloyl activated ester equivalent” is defined in the specification (p. 27, lines 4-7).

However, the specification does not provide for R is “an acryloyl activated ester equivalent” of step (b) of claim 1. As such, the instant claim 1 lacks support in the specification.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for contacting the acryloyl ester IV with a homogeneous organometallic catalyst for ring-closing metathesis, does not reasonably provide enablement for contacting with any catalyst as claimed. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art of medicinal chemistry to use the invention. Enablement is considered in view of the Wands factors (MPEP 2164.01 (A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability or unpredictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims recite a method of making compound V of step (c) from compound IV by contacting IV with a catalyst, as in any

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catalyst. The reaction performed is ring closing metathesis. These compounds are important pharmaceutically as intermediates of atorvastatin.

Breadth of the Claims: The instant claim includes the use of any catalyst. As such, hundreds of thousands of catalysts as recited in claim 1 as well as the presently unknown list of potential catalysts are embraced by claim 1.

Guidance of the specification: The direction concerning the catalysts used is found in the instant specification (p.29-30). However, it only recites homogeneous organometallic catalyst for ring closing metathesis.

State of the prior art: The reactions of ring closing metathesis are well known in the chemical arts. Most widely used catalysts for ring closing metathesis are Grubb's catalysts (e.g. *Org. Lett.* **2000**, 2(20):p. 3153-3155 provided by applicants in IDS), which many are commercially available. However, a salt such as LiCl is also a catalyst as it can increase the rate of Wittig reactions (Carey and Sundberg: *Advanced Organic Chemistry*, 3<sup>rd</sup> Ed., Part B: Reactions and Synthesis, Plenum Press, NY., **1990** p. 101)

Existence of working examples/specification: There are working examples of organometallic catalysts for ring closing metathesis in the references cited by applicants on p. 29-30 of the specification and applicants' own work on p. 35. There is no working example of any catalyst being used for ring closing metathesis reactions.

The skill of those in the art: The artisans following Applicants' procedures are synthetic chemists most probably with a Ph. D. degree.

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The predictability or unpredictability of the art: It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved”. So far, metathesis reactions require specialized conditions and catalysts in order to be performed successfully.

Amount of experimentation necessary: Finding any other catalyst besides the currently well known catalysts to perform ring closing metathesis in the reaction of step (c) of claims 1 is an empirical exercise. Predicting if a certain catalyst, will in fact produce the reaction is filled with experimental uncertainty and requires a large quantity of experimentation.

MPEP 2164.01(a) states, “[a] conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).” That conclusion is clearly justified here. Thus, undue experimentation will be required to determine if any catalyst claimed will, in fact, produce the reaction claimed.

### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: Step (b) of claim 1 is confusing where it states “the acryloyl ester of” and is followed by a pictured compound with no number. It could easily be understood that the acryloyl ester mentioned is of that pictured compound and not of formula (IV). Appropriate correction is required.

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4. Dependent Claims 2-5 are objected to as being dependent upon a rejected based claim.

***Allowable Subject Matter***

Claims 6-7 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VRG

/Kamal A Saeed,./  
Primary Examiner, Art Unit 1626